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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/629,771	07/31/2000	Mark H. Wyzgala	BSC0114052	5428

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EXAMINER

LEWIS, RALPH A

ART UNIT	PAPER NUMBER
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3732

DATE MAILED: 08/01/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/629,771

Applicant(s)

Wyzgala et al

Examiner

Ralph Lewis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 11 6) ☐ Other: _____

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Rejections based on 35 U.S.C. 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 29 and 30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 29, line 1, there is no antecedent basis for "[t]he reverse pull-back device." In lines 1 and 2, there is no antecedent basis for "the polymeric balloon section."

In claim 30, line 1, there is no antecedent basis for "[t]he reverse pull-back device." In line 2, there is no antecedent basis for "the wire mesh."

Rejections based on Obvious-type Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper tames extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.d. 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground

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provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-31 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-25 of U.S. Patent No. 6096,054. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of '054 set forth the currently claimed drive shaft ('054 claim 1), expandable polymeric ablation burr ('054 claims 1, 6) and "expansion control system" ('054 claims 4, 11) as well as the method of use ('054 claims 24, 25). Merely setting forth the claimed '054 in the terms of the present claims would have been obvious to one of ordinary skill in the art.

Rejections based on Prior Art

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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Claims 1, 2, 6, 9, 11-13 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Lefebvre (5,376,100).

Lefebvre discloses an atherectomy device for ablating occlusions within a patient's blood vessels comprised of a drive shaft 2 with an ablation burr 3 attached thereto. The ablation burr 3 is comprised of a polymeric (PTFE) tube section which expands from a first diameter (Fig 1B) to an enlarged second diameter (Fig 1A) when rotated (note column 4, lines 55-61). The ablation burr 3 includes an abrasive coating (note column 6, lines 12-18). The "expansion control system to control the expansion of the burr" limitation is met simply by the flexibility of the PTFE material of the burr 3, the length of its slits and/or the speed of rotation (note column 2, lines 55-58).. In regard to claim 9, cross linking occurs in all polymers. In regard to claim 11, note nose section 9. In regard to claims 12 and 13, note the stepped nose portion between 9 and 12. In regard to method claim 19, note that the ablation burr 3 is pushed and pulled through the lesion (see column 5, lines 27-30).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 1, 2, 9, 14, 15 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Taheri (4,465,072) optionally in view of Shuturman et al (5,897,566).

Taheri discloses a device for removing occlusions within a patient's blood vessel comprising a drive shaft 12 and ablation burr 13 secured to the drive shaft wherein the burr 13 is comprised of a polymeric material in the shape of a tube (balloon) which is expanded from a first to a second larger diameter. The Taheri expandable polymeric burr includes a "plurality of outwardly-extending abrasive burr-like pips or ribs on its outer surface" (column 3, lines 7-10) to scrape or thrombose the walls of the blood vessel. The Taheri abrasive pips or ribs do not reasonably meet the "abrasive coating disposed on" limitation, however, one of ordinary skill in the art would have readily appreciated that a conventional abrasive coating could have been applied in place of the abrasive pips disclosed by Taheri as an obvious substitution of conventional abrasives. The substitution is particularly obvious in view of Shuturman et al who disclose the use of an abrasive coating on a burr for removing deposits within a patient's blood vessels. To have used an abrasive coating on the Taheri burr rather than the disclosed abrasive pips would have been obvious to one of ordinary skill in the art in view of the Shuturman et al teaching of the appropriateness for using an abrasive coating on a burr for removing blood vessel deposits.

Claims 3 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Taheri (4,465,072)and Shuturman et al (5,897,566) as applied above with respect to claim 1 and in further view of Andersen et al (4,706,670).

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Andersen et al teach that it is desirable to reinforce balloon catheters with embedded fibers in order to provide for uniform consistent expansion of the balloon. To have added embedded reinforcing fibers to the Taheri balloon catheter in order to provide for uniform consistent expansion of the balloon would have been obvious to one of ordinary skill in the art

Claims 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lefebvre (5,376,100) in view of Plassche, Jr. et al (5,318,576).

Lefebvre fails to disclose the claimed curvilinear ribs disposed on the inside surface of the burr for controlling the expansion of the burr 3. Plassche, Jr. et al, however, for a an atherectomy device very similar to that of Lefebvre teaches that it is desirable to provide the burr expansion members 15e with curvilinear ribs 86 (note Figures 7A, 7B and 8) for controlling the expansion of the burr. To have provided the Lefebvre expandable burr 3 with curvilinear ribs as taught by Plassche, Jr. et al in order to control the expansion of the burr would have been obvious to one of ordinary skill in the art.

Claims 20-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lefebvre (5,376,100) in view of Carbo et al (5,250,060).

Lefebvre fails to disclose the claimed aspiration step, expanding seal step and balloon section for creating a seal step. Carbo et al, however, for a similar atherectomy device teaches that it is desirable to provide for a balloon 42 downstream of the lesion and a balloon 44 upstream

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of the lesion for sealing the part of the lesion being worked upon so that the debris may flushed and aspirated from the site. To have provided the Lefebvre atherectomy device with similar upstream and downstream balloons so that the work site may be flushed of debris as taught by Carbo et al would have been obvious to one of ordinary skill in the art.

Allowable Subject Matter

Claims 23-28 and 31 would be allowed upon the filing of a terminal disclaimer to overcome the obvious-type double patenting rejection above.

Claims 4, 5, 16 and 18 would be allowable if rewritten in independent form to include all of the limitations of the claims from which they depend and upon the filing of a terminal disclaimer to overcome the obvious-type double patenting rejection above.

Claims 29 and 30 would be allowable if rewritten to overcome the rejections based on 35 U.S.C. 112, second paragraph above (i.e. amended to depend from claims 28 and 29, respectively) and upon the filing of a terminal disclaimer to overcome the obvious-type double patenting rejection above.

Prior Art

Applicant's information disclosure statements of June 25, 2002 and November 09, 2000 have been considered and an initialed copy enclosed herewith. As a side note, it is unclear what


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patent 5,385,311 directed to earth moving construction equipment possibly has to do with the disclosed invention.

Zacca et al (5,308,354), Hart et al (5,868,708), Ressemann et al (5,897,567) and Wyzgala et al (6,416,526) are made of record.

Any inquiry concerning this communication should be directed to Ralph Lewis at telephone number (703) 308-0770. Fax (703) 872-9302. The examiner works a compressed work schedule and is unavailable every other Friday.

R.Lewis
July 25, 2002



Ralph A. Lewis
Primary Examiner
Au 3732